PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Thomas S. Wilson et al	Examiner: Kathleen C. Sonnett	
Serial No.:	10/801,355	Art Unit: 3731	
Filed:	03/15/2004	Attorney Docket No.: IL-11176	
Title:	SHAPE MEMORY POLYMER FOAMS FOR ENDOVASCULAR THERAPIES		

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANT'S REPLY BRIEF (37 C.F.R. § 1.192)

This Reply Brief is submitted in response to the "Examiner's Answer" mailed August 18, 2009. Appellants' Appeal Brief is relied upon as responding to the issues in the Examiner's Answer; however, Appellants provide this Reply Brief with the following additional responses to specific points in the Examiner's Answer mailed August 18, 2009. One copy of the Reply Brief is being transmitted per 37 C.F.R. § 41.37.

STATUS OF CLAIMS

The application as originally filed contained claims 1-56.

The claims on appeal are claims 1-56.

The status of all the claims in the proceeding (*e.g.*, rejected, allowed or confirmed, withdrawn, objected to, canceled) is:

Claims 1-56 are rejected.

Claims 1-56 are reproduced in the Appendix of Appellants' Appeal Brief.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Final Rejection and the Examiner's Answer state the nine (9) grounds of rejection summarized below.

Grounds of Rejection #1 - Claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland et al U.S. Published Patent Application No. 200210095169 (hereinafter "Maitland") in view of Bleys et al U.S. Patent No. 6,034,149 (hereinafter "Bleys").

Grounds of Rejection #2 - Claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya et al U.S. Patent No. 5,192,301 (hereinafter "Kamiya") in view of Bleys.

Grounds of Rejection #3 - Claims 2 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland in view of Bleys and further in view of Picha U.S. Patent No. 5,207,709 (hereafter "Pica").

Grounds of Rejection #4 - Claims 2, 24, and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya in view of Bleys and further in view of Picha.

Grounds of Rejection #5 - Claims 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya in view of Bleys and further in view of Linden et al U.S. Patent No. 5,634,936 (hereinafter "Linden").

Grounds of Rejection #6 - Claims 17-20 and 39-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya or Maitland in view of Bleys and further in view of Porter U.S. Published Patent Application No. 2002/0165582 (hereinafter "Porter").

Grounds of Rejection #7 - Claims 48 and 50-52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya in view of Bleys and further in view of Maitland.

Grounds of Rejection #8 - Claims 53-56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya in view of Bleys and further in view of Porter.

Grounds of Rejection #9 - Claims 16 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland.

REPLY TO GROUNDS OF REJECTION #1

(Claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 rejected under 35 U.S.C. § 103(a) as unpatentable over Maitland in view of Bleys)

The Examiner's Answer in the middle paragraph on page 3 contains the following statement:

> "Maitland discloses an apparatus for occluding a physical anomaly comprising a shape memory polymer for positioning in the interior of the physical anomaly and a system for providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly (see abstract)."

Appellants respectfully disagree with the quoted statement. The statement is not supported by the facts. The Maitland reference does not disclose "an apparatus for occluding a physical anomaly." Text from the Maitland reference is quoted below showing that the Maitland reference only discloses "an actuator system ... removing matter from a vessel" and does not disclose an apparatus for occluding a physical anomaly.

> "SUMMARY OF THE INVENTION
> [0018] The present invention provides an actuator system. The system uses heat to activate a shape memory material. The shape memory material will change shape when heated above a transition temperature. The shape memory material is adapted to move from a first shape to a second shape where it can perform a desired function. In one embodiment of the present invention a method of removing matter from a vessel is described. A catheter with a shape memory material is transported to the site of the matter to be removed. The shape memory material is passed through or around the matter. Heat is utilized to activate the shape memory material and expand the shape memory material. By withdrawing the catheter and the shape memory material through said vessel the matter is carried from the vessel." (Paragraph [0018] from Maitland Reference)

The Examiner's Answer in the middle paragraph on page 3 contains the following statement:

> "The apparatus also comprises a delivery system (30 and 32 or 12) capable of delivering the shape memory material body into the interior of the physical anomaly."

Appellants respectfully disagree with the statement. The statement is not supported by the facts. The Maitland reference only shows "removing matter from a vessel." In the Maitland reference "a catheter with a shape memory material is transported to the site of the matter to be removed. The shape memory material is passed through or around the matter. Heat is utilized to activate the shape memory material and expand the shape memory material. By withdrawing the catheter and the shape memory material through said vessel the matter is carried from the vessel." The Maitland reference is basically the opposite of Appellants' claimed invention in that the Maitland reference removes a clot whereas Appellants' claimed invention inserts a shape memory material body in an aneurism.

The Maitland reference lacks many apparatus claim elements of Appellants' claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44. Note that the Maitland reference lacks Appellants' apparatus claim elements from Appellants' independent claims listed below.

> Independent Claim 1
> "a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam;"
>
> "a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly;"
>
> "a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly."

Independent Claim 23

"shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam;"

"a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism;"

"an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism."

Since the Maitland reference lacks Appellants' apparatus claim elements identified above the Examiner's Answer does not meet Criterion 1 for the Examiner to establish a *prima facie* case of obviousness.

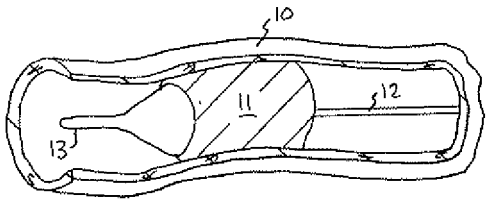
The Examiner's Answer in the middle paragraph on page 11 contains the following statement:

> "In response to appellant's argument that the device of Maitland is not disclosed as being used for occluding a physical anomaly and is instead disclosed as being used for removing a clot in a vein or artery, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Maitland discloses an apparatus comprising the claimed structure of a shape memory material (13), a delivery system for delivering the shape memory material body (12), and a system for providing the shape memory material with a primary and secondary shape (paragraph 57). If the apparatus is delivered such that the shape memory material (13) is placed within a physical anomaly, such as an aneurysm, the material is capable of occluding the physical anomaly once it has been expanded to fill the anomaly."

Appellants respectfully disagree with the quoted statement. The statement is not supported by the facts. The Maitland reference system removes a clot from a blood vessel whereas Appellants' claimed invention inserts a shape memory material body in an aneurism. Contrary to the statement in the Examiner's Answer, the Maitland reference does not disclose "a delivery system for delivering the shape memory material body (12)." FIG. 1 from the Maitland reference is

reproduced below illustrating that in the Maitland reference a blockage 11 is being removed from a vessel 10.

FIG. 1



The text of paragraph [0056] from the Maitland reference is reproduced below wherein FIG. 1 is described.

> [0056] FIG. 1 shows a vessel **10** with a blockage **11**. The blockage could be a blood clot, plaque, other emboli, or other blockage. A support structure **12** with a shape memory material actuator **13** on its distal end is inserted through or around the blockage **11**. The shape memory material actuator **13** is used to remove the blockage **11** from the vascular system.

The Maitland reference paragraph [0056] text specifically states that a blockage 11 is being removed from a vessel 10. The Maitland reference system is basically the opposite of Appellants' claimed invention in that the Maitland reference removes a blockage 11 from a blood vessel 10 whereas in Appellants' claimed invention a shape memory material is inserted in an aneurism.

Since the Maitland reference is substantially different from Appellants' invention the Examiner's Answer does not meet Criterion 2 for the Examiner to establish a *prima facie* case of obviousness because the proposed combination of the Maitland reference and the Bleys reference would not have a reasonable expectation of success and would not produce Appellants' claimed invention. The Examiner's Answer does not meet Criterion 3 for the Examiner to establish a *prima facie* case of obviousness because the Examiner's Answer reasons for the proposed combination are based upon an incorrect analysis of the facts.

The combination of the Maitland and Bleys references in the Examiner's Answer fails to meet Criteria 1, 2, and 3 required for the Examiner to establish a *prima facie* case of obviousness and fails to support a rejection of claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 under 35 U.S.C. § 103(a). The rejection of Appellants' claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 in Grounds of Rejection #1 should be reversed.

REPLY TO GROUNDS OF REJECTION #2

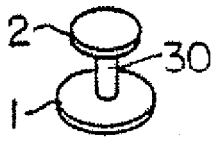
(Claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 rejected under 35 U.S.C. § 103(a) as unpatentable over Kamiya in view of Bleys)

The Examiner's Answer in the last full paragraph on page 5 contains the following statement:

> "It would have been obvious to one of ordinary skill in the art to modify the device of Kamiya to choose the shape memory foam of Bleys for the shape memory material body because of its biocompatibility (column 6 lines 45-51)."

Appellants respectfully disagree with the quoted statement. It would not be obvious to use the shape memory foam of Bleys for the shape memory polymer closing plug of Kamiya because the Kamiya device would not be operative with the Bleys shape memory polymer foam. The Kamiya closing plug has a flange at one end which is made of a shape memory polymer. The Kamiya closing plug must be of a solid shape to close the defect. The Kamiya closing plug flange could not be made of a shape memory polymer foam. The shape memory polymer foam would not operate as a flange and the Kamiya device would not form the closing plug that is the subject of the Kamiya reference. FIG. 1 from the Kamiya reference is reproduced below.

F I G. 1



The Kamiya reference describes FIG. 1 as follows: "FIG. 1 shown the basic shape of the closing plug, which as two flanges, 1, 2 of different size, being fixed at both ends of a cylindrical member 30. The flanges 1, 2 of FIG. 1 are folded inward or outward so that they have a decreased size. After the closing plug is inserted into the defect (i.e., an opening in a body part, the opening having a rim or peripheral edge defining a boundary of the opening), the flanges restore to their original shape as shown in FIG. 1, fix the closing plug to the defect and hold it from both sides of the wall of the body part and, at the same time, the passage of the fluid through the defect stops."

The Kamiya reference in Column 2, lines 48-52 describes the closing plug as follows:

> "To secure the fixing of the closing plug at the defect, a flange or the like must be placed at the end of the closing plug and it must be located on the side of higher fluid pressure."

The Kamiya closing plug must have a flange at the end of the closing plug and the flange must be located on the side of higher pressure to close the defect. Appellants' foam would not be operative as a flange.

The Kamiya reference in Column 3, lines 16-26 describes the closing plug as follows:

> "In the closing plug, a shape memory polymer is molded to a shape suitable for closing a defect in a body part. The molded closing plug is then deformed to a decreased size suitable to insert easily into the body part above the shape recovery temperature of the polymer and is then cooled to fix the plug to the deformed decreased-size shape. Thus, the deformed closing plug is inserted to the desired

location in the body and is then warmed to above the shape recovery temperature to recover the original shape suitable for closing the body defect."

The Kamiya closing plug must be "molded to a shape suitable for closing a defect in a body part." Appellants' foam would not be operative to be "molded to a shape suitable for closing a defect in a body part."

In the Kamiya reference "The molded closing plug is then deformed to a decreased size suitable to insert easily into the body part." Appellants' foam would not retain the desired shape when "the molded closing plug is then deformed to a decreased size suitable to insert easily into the body part."

In the Kamiya reference the molded closing plug is "cooled to fix the plug to the deformed decreased-size shape." Appellants' foam would not retain the desired shape when "cooled to fix the plug to the deformed decreased-size shape."

The Kamiya reference lacks many apparatus claim elements of Appellants' claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49. Note that the Kamiya reference lacks Appellants' apparatus claim elements from Appellants' independent claims listed below.

Independent Claim 1
"a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam;"

"a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly;"

"a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly."

Independent Claim 23
"shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam;"

> "a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism;"
>
> "an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism."

Since the Kamiya reference lacks Appellants' apparatus claim elements identified above the Examiner's Answer does not meet Criterion 1 for the Examiner to establish a *prima facie* case of obviousness. The Kamiya device is "a closing plug for therapeutic use within a body duct or defect." A closing plug for a body duct or defect is not Appellants' claimed shape memory polymer foam for being positioned in the interior of the aneurism." The basic shape of the Kamiya closing plug, which as two flanges, 1, 2 of different size, being fixed at both ends of a cylindrical member 30. The Kamiya reference is substantially different from Appellants' invention the Examiner's Answer does not meet Criterion 2 for the Examiner to establish a *prima facie* case of obviousness because the proposed combination of the Kamiya reference and the Bleys reference would not have a reasonable expectation of success and would not produce Appellants' claimed invention.

The Kamiya reference does not show Appellants claimed "delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism" or "an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism." The Examiner's Answer does not meet Criterion 3 for the Examiner to establish a *prima facie* case of obviousness because the Examiner's Answer reasons for the proposed combination are based upon an incorrect analysis of the facts.

The combination of the Kamiya and Bleys references in the Examiner's Answer fails to meet Criteria 1, 2, and 3 required for the Examiner to establish a *prima facie* case of obviousness and fails to support a rejection of claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 under 35 U.S.C. § 103(a). The rejection of Appellants' claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 in Grounds of Rejection #2 should be reversed.

REPLY TO GROUNDS OF REJECTION #3

(Claims 2 and 24 rejected under 35 U.S.C. § 103(a) as unpatentable over Maitland in view of Bleys and further in view of Pica)

The Examiner's Answer in the last full paragraph on page 6 contains the following statement:

> "It would have been obvious to size the open cells of the shape memory foam of Maitland in view of Bleys so that the pores are between 10 and 50 microns since Picha teaches that such pore sizes allows tissue ingrowth."

Appellants respectfully disagree with the quoted statement. The Pica reference "Implant with Textured Surface" has nothing to do with the Maitland system for removing a blood clot or the Bleys hydrophilic polyurethane foams. There would be no reason for combining the Pica reference with the Maitland reference with the Bleys reference. The statement in the Examiner's Answer that the combination would be obvious "since Picha teaches that such pore sizes allows tissue ingrowth" is not a reason for making a combination of such different systems as the Pica reference "Implant with Textured Surface" and the Maitland system for removing a blood clot and the Bleys hydrophilic polyurethane foams.

The Examiner's Answer in the first full paragraph on page 13 contains the following statement:

> "However, the rejection includes that it would have been obvious to size the open cells of the shape memory foam of Maitland in view of Bleys so that the pores are between 10 and 50 microns as taught by Picha because this pore size induces blood vessel proximity and neovascularization of the implant (column 8, lines 41-46)."

Appellants respectfully disagree with the quoted statement, particularly the portion of the statement "the shape memory foam of Maitland." This statement conflicts with other statements in the Examiner's Answer that "Maitland fails to disclose that the shape memory material body comprises a shape memory polymer foam." See the last sentence of the middle paragraph on page 3 of the Examiner's Answer.

The combination of the Maitland, Bleys, and Pica references in the Examiner's Answer fails to meet Criteria 1, 2, and 3 required for the Examiner to establish a *prima facie* case of obviousness and fails to support a rejection of claims 2 and 24 under 35 U.S.C. § 103(a). The rejection of Appellants' claims 2 and 24 in Grounds of Rejection #3 should be reversed.

REPLY TO GROUNDS OF REJECTION #4

(Claims 2, 24, and 46 rejected under 35 U.S.C. § 103(a) as unpatentable over Kamiya in view of Bleys and further in view of Pica)

The Examiner's Answer in the last full paragraph on page 6 contains the following statement:

> "It would have been obvious to size the open cells of the shape memory foam of Kamiya in view of Bleys so that the pores are between 10 and 50 microns since Picha teaches that such pore sizes allows tissue ingrowth."

Appellants respectfully disagree with the quoted statement. The Pica reference "Implant with Textured Surface" has nothing to do with the Kamiya closing plug or the Bleys hydrophilic polyurethane foams. There would be no reason for combining the Pica reference with the Kamiya reference with the Bleys

reference. The statement in the Examiner's Answer that the combination would be obvious "since Picha teaches that such pore sizes allows tissue ingrowth" is not a reason for making a combination of such different systems as the Pica reference "Implant with Textured Surface" and the Kamiya closing plug and the Bleys hydrophilic polyurethane foams.

The combination of the Kamiya, Bleys, and Pica references in the Examiner's Answer fails to meet Criteria 1, 2, and 3 required for the Examiner to establish a *prima facie* case of obviousness and fails to support a rejection of claims 2, 24, and 46 under 35 U.S.C. § 103(a). The rejection of Appellants' claims 2, 24, and 46 in Grounds of Rejection #4 should be reversed.

REPLY TO GROUNDS OF REJECTION #5

(Claim 5 rejected under 35 U.S.C. § 103(a) as unpatentable over Kamiya in view of Bleys and further in view of Linden)

The Examiner's Answer in the last paragraph on page 7 contains the following statement:

> "It would have been obvious to one skilled in the art to modify the device of Kamiya to include dissolving the polymer foam within solution of DMSO since Linden teaches that such solvents paired with foams are well known and can be used to keep the foam soft prior to deployment."

Appellants respectfully disagree with the quoted statement. The Linden reference "device for closing a cardiovascular or cardiac septal defect" has nothing to do with the Kamiya closing plug or the Bleys hydrophilic polyurethane foams. There would be no reason for combining the Linden reference with the Kamiya reference with the Bleys reference. The statement in the Examiner's Answer that "Linden teaches that such solvents paired with foams are well known and can be used to keep the foam soft prior to deployment" is not a reason for making a

combination of such different systems as the Linden reference "device for closing a cardiovascular or cardiac septal defect" and the Kamiya closing plug and the Bleys hydrophilic polyurethane foams.

The combination of the Kamiya, Bleys, and Linden references in the Examiner's Answer fails to meet Criteria 1, 2, and 3 required for the Examiner to establish a *prima facie* case of obviousness and fails to support a rejection of claim 5 under 35 U.S.C. § 103(a). The rejection of Appellants' claim 5 in Grounds of Rejection #5 should be reversed.

REPLY TO GROUNDS OF REJECTION #7

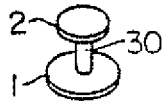
(Claims 48 and 50-52 rejected under 35 U.S.C. § 103(a) as unpatentable over Kamiya in view of Bleys and further in view of Maitland)

The Examiner's Answer in the last paragraph on page 14 contains the following statement:

> "It would have been obvious to one of ordinary skill in the art to modify the method of Kamiya to include using an optical fiber and laser to transmit laser light through the optical fiber to heat the shape memory body without causing surrounding trauma."

Appellants respectfully disagree with the quoted statement. FIG. 1 from the Kamiya reference is reproduced below.

FIG. 1



The Kamiya reference describes FIG. 1 as follows:

> "FIG. 1 shown the basic shape of the closing plug, which as two flanges, 1, 2 of different size, being fixed at both ends of a cylindrical member 30. The flanges 1, 2 of FIG. 1 are folded inward or outward so that they have a decreased size. After the closing plug is inserted into the defect (i.e., an opening in a body part, the

> opening having a rim or peripheral edge defining a boundary of the opening), the flanges restore to their original shape as shown in FIG. 1, fix the closing plug to the defect and hold it from both sides of the wall of the body part and, at the same time, the passage of the fluid through the defect stops."

The Kamiya reference describes changing the shape of the closing plug as follows:

> "The temperature of the closing plug can be accurately controlled by passing physiological saline at a temperature of, for example, 25. degree. C. through the catheter 22 and thus the unfavorable recovery of the original shape during the insertion is securely prevented." (Column 8, lines 20-24 of the Kamiya Reference)

> "After the closing plug is fitted to the defect, the shape of the closing plug can be recovered to the original shape by stopping the injection of cold water through the catheter and the hole is closed." (Column 8, lines 31-34 of the Kamiya Reference)

In the Kamiya reference the recovery to the original shape of the closing plug is accomplished using body heat. There is no suggestion or reason for "using an optical fiber and laser to transmit laser light through the optical fiber to heat the shape memory body" as alleged in the above statement from the Examiner's answer. It would not be obvious to combine the Maitland laser and optical fiber system with the Kamiya reference because the Kamiya reference uses body heat for the recovery of the original shape of the closing plug .

The Kamiya reference in Column 3, lines 16-26 describes the closing plug as follows:

> "In the closing plug, a shape memory polymer is molded to a shape suitable for closing a defect in a body part. The molded closing plug is then deformed to a decreased size suitable to insert easily into the body part above the shape recovery temperature of the polymer and is then cooled to fix the plug to the deformed decreased-size shape. Thus, the deformed closing plug is inserted to the desired location in the body and is then warmed to above the shape recovery temperature to recover the original shape suitable for closing the body defect."

The Kamiya closing plug must be "molded to a shape suitable for closing a defect in a body part." Appellants' foam would not be operative to be "molded to a shape suitable for closing a defect in a body part." In the Kamiya reference "The

molded closing plug is then deformed to a decreased size suitable to insert easily into the body part." Appellants' foam would not retain the desired shape when "the molded closing plug is then deformed to a decreased size suitable to insert easily into the body part." In the Kamiya reference the molded closing plug is "cooled to fix the plug to the deformed decreased-size shape." Appellants' foam would not retain the desired shape when "cooled to fix the plug to the deformed decreased-size shape."

There would be no reason for combining the Maitland reference with the Kamiya reference with the Bleys reference. The combination of the Kamiya, Bleys, and Maitland references in the Examiner's Answer fails to meet Criteria 1, 2, and 3 required for the Examiner to establish a *prima facie* case of obviousness and fails to support a rejection of claims 48 and 50-52 under 35 U.S.C. § 103(a). The rejection of Appellants' claims 48 and 50-52 in Grounds of Rejection #7 should be reversed.

REPLY TO GROUNDS OF REJECTION #8

(Claims 53-56 rejected under 35 U.S.C. § 103(a) as unpatentable over Kamiya in view of Bleys and further in view of Porter)

The Examiner's Answer in the first full paragraph on page 14 contains the following statement:

> "However, these rejections includes that Porter teaches the use of magnetic microparticles dispersed in a polymer that can selectively absorb RF radiation converting It to heat. These microparticles provide point sources of heat that do not cause significant tissue damage around the implantation site (par. 82). Providing such a system in the body of Kamiya of Maitland would allow the use of materials with transition temperatures further away from body temperature without risking damage to tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Maitland or Kamiya to include magnetic microparticles as made obvious by Porter in order to have a convenient point heat source and to be able to use of a shape memory material with a higher transition temperature."

Appellants respectfully disagree with the quoted statement. The Kamiya reference describes changing the shape of the closing plug as follows:

> "The temperature of the closing plug can be accurately controlled by passing physiological saline at a temperature of, for example, 25. degree. C. through the catheter 22 and thus the unfavorable recovery of the original shape during the insertion is securely prevented." (Column 8, lines 20-24 of the Kamiya Reference)
>
> "After the closing plug is fitted to the defect, the shape of the closing plug can be recovered to the original shape by stopping the injection of cold water through the catheter and the hole is closed." (Column 8, lines 31-34 of the Kamiya Reference)

In the Kamiya reference the recovery to the original shape of the closing plug is accomplished using body heat. There is no suggestion or reason for using the "Porter ... magnetic microparticles dispersed in a polymer that can selectively absorb RF radiation converting it to heat" as alleged in the above statement from the Examiner's answer. It would not be obvious to combine the Porter magnetic microparticles dispersed in a polymer that can selectively absorb RF radiation converting it to heat with the Kamiya reference because the Kamiya reference uses body heat for the recovery of the original shape of the closing plug .

The Kamiya reference in Column 3, lines 16-26 describes the closing plug as follows:

> "In the closing plug, a shape memory polymer is molded to a shape suitable for closing a defect in a body part. The molded closing plug is then deformed to a decreased size suitable to insert easily into the body part above the shape recovery temperature of the polymer and is then cooled to fix the plug to the deformed decreased-size shape. Thus, the deformed closing plug is inserted to the desired location in the body and is then warmed to above the shape recovery temperature to recover the original shape suitable for closing the body defect."

The Kamiya closing plug must be "molded to a shape suitable for closing a defect in a body part." Appellants' foam would not be operative to be "molded to a shape suitable for closing a defect in a body part." In the Kamiya reference "The molded closing plug is then deformed to a decreased size suitable to insert easily

into the body part." Appellants' foam would not retain the desired shape when "the molded closing plug is then deformed to a decreased size suitable to insert easily into the body part." In the Kamiya reference the molded closing plug is "cooled to fix the plug to the deformed decreased-size shape." Appellants' foam would not retain the desired shape when "cooled to fix the plug to the deformed decreased-size shape."

There would be no reason for combining the Porter reference with the Kamiya reference with the Bleys reference. The combination of the Kamiya, Bleys, and Porter references in the Examiner's Answer fails to meet Criteria 1, 2, and 3 required for the Examiner to establish a *prima facie* case of obviousness and fails to support a rejection of claims 53-56 under 35 U.S.C. § 103(a). The rejection of Appellants' claims 53-56 in Grounds of Rejection #8 should be reversed.

REPLY TO GROUNDS OF REJECTION #1

(Claims 16 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland)

The Examiner's Answer in the first paragraph on page 15 contains the following statement:

> "Maitland discloses including a light absorbing material in the polymer but does not expressly disclose including the light absorbing material as a coating. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a light absorbing elastomeric coating instead of a light absorbing material because Appellant has not disclosed that the elastomeric coating provides an advantage, is used for a particular purpose, or solves a stated problem over the use of a light absorbing material located within the polymer material."

Appellants respectfully disagree with the quoted statement and points out that the Maitland reference completely fails as a reference against Appellants' invention as defined by claims 16 and 38.

Appellants' Invention

Appellants' invention is illustrated in FIGS. 1 and 2 reproduced below.

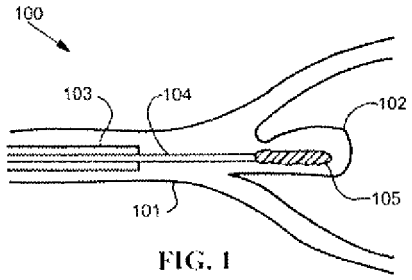


FIG. 1

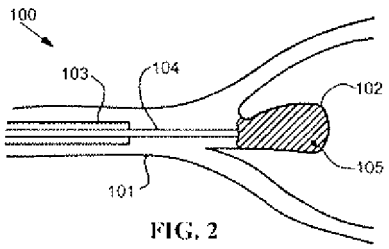


FIG. 2

Appellants' invention is described in the paragraphs of Appellants' original specification reproduced below.

[0021] Referring now to FIGS. 1 and 2, two figures will be used to describe an embodiment of the present invention that provides a system for occluding a physical anolmaly. The embodiment is designated generally by the reference numeral 100. FIGS. 1 and 2 are schematic illustrations of the working end of a system 100 for treating an arteriovenous malformation or aneurysm 102. (Page 9, lines 10-14 of Appellants' original specification)

[0022] As shown in FIG. 1, a collapsed SMP foam device 105 is connected at the end of a guide wire 104. The SMP foam device 105 is placed inside the aneurysm 102. This is accomplished by delivering the SMP foam device 105 through a catheter 103 using the guide wire 104. The catheter 103 is inserted through the artery 101 to position the SMP foam device 105 in the aneurysm 102. (Page 9, lines 20-26 and page 10, lines 1-2 of Appellants' original specification)

[0023] Referring now to FIG. 2 the SMP foam device 105 is shown actuated, thereby expanding it inside the aneurysm 102 and occluding the aneurysm 102. The SMP foam device 105 is expandable from 100% to 10000% in volume. The SMP foam device 105 is actuated by one of several means including electromagnetic energy delivered optically. The SMP foam device 105 is used to occlude part or all of a lumen, aneurysm, or artiovascular malformation. The expanded SMP foam device 105 is releasing from the end of the guide wire 104. The guide wire 104 is then retracted through the catheter 103. The catheter 103 is then retracted from the artery 101. (Page 10, lines 3-8 of Appellants' original specification)

[0025] The present invention has uses wherever it is desirable to occlude a physical anomaly. For example, the present invention has use for the closure of an aneurysm for the prevention and/or treatment of a stroke. (Page 10, lines 24-26 of Appellants' original specification)

Appellants' invention is defined by claims 16 and 38 reproduced below.

Parent Claim 1. An apparatus for endovascular therapy by occluding a physical anomaly, said anomaly having an interior, comprising:

a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam;

a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly; and

a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly.

Claim 16. The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing dye in an elastomeric coating on said shape memory material body that comprises a shape memory polymer foam.

Parent Claim 23. An apparatus for endovascular therapy by occluding-an aneurism having an interior, comprising:

shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam;

a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism; and

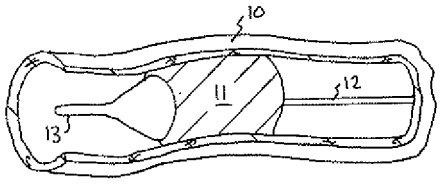
an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism.

Claim 38. The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing dye in an elastomeric coating on said shape memory material body that comprises a shape memory polymer foam.

The Maitland Reference

The Maitland reference system removes a clot from a blood vessel as contrasted with Appellants' claimed invention that inserts a shape memory foam body in an aneurism. FIG. 1 from the Maitland reference is reproduced below illustrating that in the Maitland reference a blockage 11 is being removed from a vessel 10.

FIG. 1



The text of paragraph [0056] from the Maitland reference is reproduced below wherein FIG. 1 is described.

> [0056] FIG. 1 shows a vessel **10** with a blockage **11**. The blockage could be a blood clot, plaque, other emboli, or other blockage. A support structure **12** with a shape memory material actuator **13** on its distal end is inserted through or around the blockage **11**. The shape memory material actuator **13** is used to remove the blockage **11** from the vascular system.

The Maitland reference paragraph [0056] text specifically states that a blockage 11 is being removed from a vessel 10. The Maitland reference system is basically the opposite of Appellants' claimed invention in that the Maitland reference removes a blockage 11 from a blood vessel 10 whereas in Appellants' claimed invention a shape memory polymer foam is inserted in an aneurism.

Maitland Reference Fails as a 35 U.S.C. § 103(a) Reference

The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness under 35 U.S.C. § 103(a). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness.

> Criterion #1 - The prior art reference must teach or suggest all the claim limitations.
>
> Criterion #2 - There must be a reasonable expectation of success with the proposed combination.
>
> Criterion #3 - The Examiner must provide reasons for combining or modifying the references to produce the proposed combination.

Criterion #1

The Maitland reference lacks many claim elements of Appellants' claims 16 and 38. The Maitland reference lacks Appellants' claim elements listed below.

Parent Claim 1
"a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam;"

"a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly;"

"a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly."

Claim 16
"The apparatus of claim 1 wherein said system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing dye in an elastomeric coating on said shape memory material body that comprises a shape memory polymer foam."

Parent Claim 23
"shape memory polymer material body for being positioned in the interior of the aneurism, wherein said shape memory polymer material body comprises a shape memory polymer foam;"

"a delivery system for delivering said shape memory polymer material body that comprises a shape memory polymer foam into the interior of the aneurism;"

"an activation system for providing said shape memory polymer material body with a primary shape for occluding the aneurism and a secondary shape for being positioned in the interior of the aneurism."

Claim 38
"The apparatus of claim 23 wherein said activation system for providing said shape memory polymer material body that comprises a shape memory polymer foam with a primary shape and a secondary shape comprises a light absorbing dye in an elastomeric coating on said shape memory material body that comprises a shape memory polymer foam."

Since the Maitland reference lacks Appellants' claim elements identified above the Examiner's Answer does not meet Criterion 1 for the Examiner to

establish a *prima facie* case of obviousness. The rejection of Appellants' claims 16 and 38 in Grounds of Rejection #9 should be reversed.

Criterion #2

The Maitland reference system is basically the opposite of Appellants' claimed invention in that the Maitland reference removes a blockage 11 from a blood vessel 10 whereas in Appellants' claimed invention a shape memory polymer foam is inserted in an aneurism. Since the Maitland reference is substantially different from Appellants' invention the Examiner's Answer does not meet Criterion 2 for the Examiner to establish a *prima facie* case of obviousness because the Maitland reference would not have a reasonable expectation of success and would not produce Appellants' claimed invention defined by claims 16 and 38. The Examiner's Answer does not meet Criterion 2 for the Examiner to establish a *prima facie* case of obviousness. The rejection of Appellants' claims 16 and 38 in Grounds of Rejection #9 should be reversed.

Criterion #3

The Examiner's Answer does not provide an explanation of how or why the Maitland reference would be modified to meet claims 16 and 38. Even if the Maitland reference was modified it still would not produce the invention of Appellants' claims 16 and 38.

The Examiner has not provided reasons for modifying the Maitland reference to produce the proposed combination. The Maitland reference fails to meet Criterion 3 required for the Examiner to establish a *prima facie* case of obviousness and fails to support a rejection of claims 16 and 38 under 35 U.S.C. § 103(a). The rejection of Appellants' claims 16 and 38 in Grounds of Rejection #9 should be reversed.

Summary

The references do not meet Criteria 1, 2, or 3 for establishing a *prima facie* case of obviousness and fail as a 35 U.S.C. § 103(a) rejection against claims 1-56 on appeal. The references fail to meet Criterion 1 because they do not teach identified claim elements of Appellants' claims 1-56. There would not be a reasonable expectation of success with the proposed reference combinations and Criterion 2 has not been met. The Examiner's Answer does not provide reasons why the references would be combined and fails to meet Criterion 3.

With regard to Grounds of Rejection #9, the Maitland reference completely fails as a 35 U.S.C. § 103(a) reference against claims 16 and 38. The Maitland reference system is basically the opposite of Appellants' claimed invention in that the Maitland reference removes a blockage from a blood vessel whereas in Appellants' claimed invention a shape memory polymer foam is inserted in an aneurism. The rejection of Appellants' claims 16 and 38 on appeal should be reversed.

The rejection of Appellants' claims on appeal should be reversed. It is respectfully requested that Appellants' claims 1-56 on appeal be allowed.

Respectfully submitted,

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